

ATTACHMENT 2

1 VIDEOTAPED ZOOM DEPOSITION OF DR. EUGENE
2 RUBACH, TAKEN ON BEHALF OF DEFENDANT, COMMENCING AT 1:01
3 P.M., WEDNESDAY, MARCH 8, 2023, AT EAST HILLS, NEW YORK,
4 BEFORE MICHELLE MEDEL SABADO, RPR, CRR, CSR #7423.
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9 APPEARANCES OF COUNSEL:

10 (ALL PARTIES APPEARING REMOTELY)
11

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11 Also Present:

12 TONY NOKES - THE VIDEOGRAPHER
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1	A	Approximately two years ago.	01:32
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2 Q When you became vice chairman of surgery at
3 St. Francis Hospital, did you take on administrative
4 responsibilities?

5	A	Yes.	01:32
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6 Q Generally, can you describe the
7 administrative responsibilities that you undertook at St.
8 Francis Hospital?

9 A They're involved with quality improvement
10 projects as related to the ICU. Some improvements to the 01:32
11 use of the electronic medical record that we have in our
12 hospital. Significant involvement with a cancer program
13 where I serve as a cancer liaison physician. Some other
14 scheduling responsibilities.

15 Q Does -- do your responsibilities as a vice 01:33
16 chair at St. Francis include any recruitment of
17 physicians?

18	A	No.
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19 Q Do you have any administrative
20 responsibilities at St. Francis which requires you to 01:33
21 consider matters that refer particularly to the da Vinci
22 Surgical System?

23 A Not specifically unless such matters come up
24 in the course of -- of operations of the hospital.

25	Q	Does St. Francis have a da Vinci Surgical	01:34
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1 If you and your counsel want to take breaks 01:50
2 less frequently after this next break, tell me that and
3 I'll try to accommodate you but I don't like -- for sure,
4 I don't like to ask the people who are working to keep
5 the record to go more than an hour and 15 or 20 minutes 01:50
6 without a break. I don't think that's right. With that
7 in mind, please, when we -- we take a break in about ten
8 minutes and if you could add that to the agenda.

9 Is that all right, Jeff?

10 MR. CORRIGAN: Yes, sure. Yes. 01:50

11 MR. RUBY: All right.

12 Q Do you consider yourself an expert in the
13 business considerations that may or may not apply to the
14 sales and marketing and utilization of the da Vinci
15 Surgical System? 01:51

16 MR. CORRIGAN: Object to the form.

17 THE WITNESS: I do not know exactly what the
18 marketing expert for da Vinci would be but I consider
19 myself an expert in the use of da Vinci Surgical Systems
20 as it pertains to the market of surgeries. 01:51

21 BY MR. RUBY:

22 Q Now when you say the "market of surgeries,"
23 what -- what market is that?

24 A That is the clinical application of surgical
25 technologies to solve surgical diseases, to cure surgical 01:52

1 Q In the course of our deposition today, if you 02:50
2 find yourself recognizing an opinion in addition to
3 paragraphs nine, ten, 11 or 12, will you tell me?

4 A I will do my absolute best.

5 Q Now paragraph 9 says -- and I'm just going to 02:51
6 read it into the record. "U.S. hospitals that do not
7 have a da Vinci robot find themselves at a great
8 disadvantage in, A, attracting well qualified surgeons
9 who practice minimally invasive surgery and B, trying to
10 appeal to patients seeking minimally invasive surgical 02:51
11 treatments."

12 We agree that that's what it says? Yes?

13 A Yes, that's what it says.

14 Q All right. What are the facts which underlie
15 the opinion that is expressed in paragraph 9? 02:51

16 A So several facts. First of all, I've been
17 sort of in the surgical world for close to 25 years now,
18 so I interact with a lot of people. I have been
19 recruited. I've been approached by recruiters on many
20 occasions for -- with job offers. I have recently in my 02:52
21 practice hired a new surgeon and I made that statement
22 based on my personal experience and interactions with
23 many surgeons, going to conferences and sort of seeing
24 how the surgical world, especially the world of minimally
25 invasive surgery that I live has developed and continues 02:52

1 to develop. 02:52

2 And I can tell you that our last most recent
3 recruit who joined our practice just a few weeks ago
4 basically does everything robotically and it would be
5 very hard for us to attract a talented young surgeon, 02:52
6 well trained surgeon at one of the most premiere surgical
7 institutions, it would be impossible for us to attract
8 into our hospital if he was -- if we didn't have a robot.
9 That would literally be responsible.

10 Now when we bring a person with such a unique 02:52
11 minimally invasive training and expertise to our
12 hospital, our hospital is now able to provide services
13 which we were not able to provide before. So now I live
14 in Long Island, New York where they have a lot of really
15 he had indicated people who, when they have a medical 02:53
16 problem other than an absolute life threatening
17 emergency, they spend a lot of times researching their
18 option. When the patients often come in to see me, they
19 already know of the medical options or treatment options
20 and the only way I could attract these people to my 02:53
21 practice is if I offer all those options because if I do
22 not, they will go someplace else. They will go to a
23 place that offers those options, so that i s-- those are
24 the facts and the realities on which I base that opinion.

25 Q Well, is it your -- strike that. 02:53

1 you including both robotic and non-robotic techniques of 02:59
2 surgery?

3 A Yes. We established that minimally invasive
4 surgery include both robotic and non-robotic approaches.

5 Q Okay. Well, you are an -- strike that. 02:59
6 Do you consider yourself an expert in the
7 economics of minimally invasive surgery?

8 A I do not generally consider myself an expert
9 in economics but I do consider myself an expert in the
10 clinical applications of minimally invasive surgery. 03:00
11 Some of it involves economics. I'm aware of the costs,
12 for example, of the equipment that they use and the
13 materials that they use or the operations they perform.

14 Q Are you appointed as -- strike that.
15 Do you consider yourself an expert in the 03:00
16 costs of minimally invasive surgery?

17 A Again, I am aware of the cost of minimally
18 invasive surgery and I understand how it affects the
19 clinical applications of it.

20 Q Okay. Do surgeons who provide minimally 03:00
21 invasive surgery, are they paid for their surgical
22 efforts?

23 MR. CORRIGAN: Object to form.

24 THE WITNESS: Generally, yes.

25 /// 03:01

1 hospital, as the hospital that cares for the patients, as 04:17
2 the hospital that is likely to provide other high end,
3 high quality services. And with that perception, it
4 increases the referrals. This is actually a term that
5 was taught to me by the Intuitive Surgical reps who were 04:17
6 very keen on selling our hospital the robot. That was
7 one of their sales pitches.

8 Q Are what you called sales pitches the factual
9 basis for what you say here in paragraphs 23 and 24?

10 A You know, not only is it a factual basis for 04:17
11 the halo effect. The opposite is now true. I don't know
12 if you want to call it the black hole effect but if the
13 hospital does not have a surgical robot, they're
14 certainly perceived -- perceived as an outlier to the
15 point that at the rate right now, not having surgical -- 04:17
16 having a surgical robot is almost expected because that
17 means that you're providing a certain degree of minimally
18 invasive surgical treatment. Not having it means that
19 you are stuck in a 20th Century.

20 Q And what is the source of the -- the 04:18
21 allegedly factual source of that opinion?

22 A The term itself, as I mentioned to you, came
23 from Intuitive Surgical reps. The -- the factual source
24 of it is my experience of living in the world of surgery
25 that I've been referring to for the last two decades, 04:18

1 interacting with my colleagues, going to conferences, 04:18
2 reading articles, speaking to people, just generally
3 being part of the world of surgery and particularly
4 minimally invasive surgery.

5 Q But what -- what is the halo effect? Is 04:18
6 it -- strike that. Withdraw that.

7 Is the halo effect different from community
8 and physician perceptions?

9 A Halo effect is a part of it. So what happens
10 is you have this halo where it is -- it's a glowing 04:19
11 hospital. It's -- it's fantastic. Everything is new.
12 Everything is modern. People who work there are well
13 qualified, well trained and they offer the most advanced
14 new minimally invasive techniques. That attracts people.
15 That attracts referring doctors. That attracts patients. 04:19
16 That creates a good vibe.

17 Q But can you give me an example of something,
18 another type of medical device other than a surgical
19 robot that creates what you call the halo effect?

20 A Yeah, I would imagine that having a 04:19
21 cyberknife would be a similar device.

22 (A pause in the proceedings.)

23 BY MR. RUBY:

24 Q Instruments for minimally invasive surgery
25 which is not robotic surgery are made out of what kind or 04:20

1 use the term? 04:22

2 A There are many barriers through which
3 somebody has to jump or over, which somebody has to jump
4 to bring a new product to the market. They involve
5 safety studies, clinical trials, comparisons to the 04:22
6 existing instruments and costs and all these things have
7 to play out in such a way so that a new instrument or a
8 new device will be brought to the market.

9 Q Is it your testimony that a new device for
10 minimally invasive surgery apart from robotic instruments 04:22
11 requires regulatory approval to be brought to market?

12 A So --

13 MR. CORRIGAN: Object to form.

14 THE WITNESS: I'm not an expert in regulatory
15 approvals and I will tell you that I have learned a lot 04:23
16 about it just reading through the documents of this
17 particular lawsuit. It appears that there are many
18 classes of devices, each one of which requires different
19 regulatory approvals and I'm by no means an expert to
20 determine which device requires what kind of approval 04:23
21 before it can be brought to the market.

22 BY MR. RUBY:

23 Q Well, today as you sit here, are you
24 convinced of the truth of the paragraph 17 which you
25 wrote and attested to? 04:23

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1 companies. 04:28

2 Q One of your opinions is that Intuitive -- I'm

3 quoting from paragraph 12. You're welcome to turn to it,

4 if you'd like. It's up to you. "Intuitive disables

5 EndoWrist instruments based on criteria which in my 04:28

6 opinion as a surgeon are arbitrary and do not reflect

7 whether an EndoWrist is suitable for clinical use."

8 Do you see that?

9 A Yes.

10 Q What criteria did you refer to? 04:29

11 A The only criterion by which the Intuitive

12 Surgical disables EndoWrist instruments is how many times

13 it was inserted into a patient while connected to a

14 robotic arm.

15 Q And you thought that was arbitrary; is that 04:29

16 right?

17 A It is my opinion this is arbitrary.

18 Q Now this is your opinion as a surgeon; is

19 that right?

20 A That's what I am, yes. 04:29

21 Q You're not an engineer; is that true?

22 A That is correct. I'm not an engineer.

23 Q Do you know anything about material science?

24 A I know very little about material science.

25 Q Do you know about durability? 04:29

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1 MR. CORRIGAN: Object to the form. 04:30

2 MR. RUBY: I - I wasn't quite finished but --

3 MR. CORRIGAN: I'm sorry.

4 MR. RUBY: -- let me start over again.

5 Q Do you know anything about durability of da 04:30

6 Vinci instruments?

7 MR. CORRIGAN: Object to the form.

8 THE WITNESS: I cannot comment about the physical

9 properties of durability of surgical instruments or da

10 Vinci instruments but I can comment on their suitability 04:30

11 for clinical use and durability to perform its intended

12 task. And this is where I have a big problem with this

13 arbitrary criteria to stop using because the same

14 instrument can be subjected to a lot of very intense use

15 and can be subjected to very little use. But the 04:30

16 instrument counter does not differentiate between those

17 two events. If instrument counter was based on the

18 actual use, it would be a completely different story.

19 BY MR. RUBY:

20 Q So you are not opposed -- well, strike that. 04:31

21 Are you opposed to the use of a usage

22 limitation feature on a minimally invasive surgery

23 instrument or are you only opposed to the -- the way that

24 you think that da Vinci -- that Intuitive has implemented

25 the feature? 04:31

1 MR. CORRIGAN: Object to the form. 04:31

2 THE WITNESS: I am not opposed to anything. What
3 I'm trying to opine on is the fact that EndoWrist
4 instruments are disabled based on the arbitrary parameter
5 that has nothing to do with their clinical usability. 04:31

6 BY MR. RUBY:

7 Q And how do you know it has nothing to do with
8 clinical usability?

9 A Because I have used instruments that were
10 within the parameters established by Intuitive Surgical 04:32
11 and they failed, despite the fact that they were used
12 less than ten times and I have seen instruments that were
13 barely used over the ten procedures and likely could have
14 been used again except it's impossible to test or to even
15 know about it without doing something to them because the 04:32
16 counter prevents these instruments from being used.

17 Q Do you, in your first report, express any
18 opinion as to the safety of EndoWrist instruments which
19 have been remanufactured according to the -- what you
20 referred to as a repair process that you heard about? 04:33

21 MR. CORRIGAN: Object to the form.

22 THE WITNESS: I have never used a remanufactured
23 EndoWrist instrument. I have used instruments in
24 training whose use counter was disabled.

25 /// 04:33

1 BY MR. RUBY: 04:33

2 Q Now would you answer my question, please.

3 A I feel that's answer to your question.

4 Q Okay. Try -- try it again.

5 A Okay. 04:33

6 Q Did you mean in your first report to express

7 an opinion as to the effectiveness? It's not a word I

8 used last time so I'll try to clarify this. Have you

9 expressed -- meant to express any opinion as to the

10 effectiveness of the remanufacturing that has been 04:33

11 offered by some of the vendors who are referred to by

12 the -- the hospitals?

13 MR. CORRIGAN: Object to the form.

14 THE WITNESS: The answer to your question is that

15 without having personal experience, it's very hard for me 04:34

16 to comment on their effectiveness. However, I have no

17 reason to suspect the effectiveness of these

18 remanufactured instruments would be any different from

19 the effectiveness of many other remanufactured and

20 repaired instruments that are routinely used in open and 04:34

21 laparoscopic surgery.

22 BY MR. RUBY:

23 Q That's your opinion?

24 A That is my opinion.

25 Q As an expert? 04:34

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1 A Was that a question? 04:34

2 Q Is that your expert opinion?

3 A Yes, that is my expert opinion.

4 Q Which is -- can you point that out to me,

5 please, in the -- your first report so I can read it and 04:34

6 make sure I've got it just right?

7 A No, I -- you -- you just asked me for an

8 opinion about the remanufactured instruments and I told

9 you I cannot have a personal opinion about it because

10 I've never used them myself. However, I have no reason 04:35

11 to suspect that these instruments would be working any

12 differently from other remanufactured instruments that I

13 use commonly in laparoscopic and open surgery.

14 Q Do you have any training or education in the

15 area of defining an antitrust market for a manufactured 04:36

16 product?

17 A No.

18 Q Do you have any education or training in the

19 discipline of economics?

20 A Not -- 04:36

21 MR. CORRIGAN: Objection.

22 THE WITNESS: Not beyond a college course.

23 BY MR. RUBY:

24 Q Pardon me?

25 A Nothing beyond a college course. 04:36

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1 Q Okay. An undergraduate course? 04:36

2 A Yes.

3 Q Econ one?

4 A I don't remember what it was called.

5 Q Have you ever used what was called the Zeus, 04:37

6 Z-E-U-S, robot?

7 A No, I have not.

8 Q Have you ever seen it in operation?

9 A Yes.

10 Q Tell me the circumstances, please. 04:37

11 A I don't remember the circumstances. It was

12 at one of the hospitals where I was for whatever reason.

13 Probably the most common experience -- like the -- the

14 most vivid experience was this sort of famous event in

15 surgical history where the very first transatlantic 04:38

16 surgery was performed with a Zeus robot. It has a name.

17 I want to say the Guttenberg operation and it was in

18 early 2000's and it was a unique experience where a

19 surgeon was actually in America and the patient was

20 actually in France and the surgeon operated on a patient 04:38

21 using a Zeus robot.

22 Q Did you witness that event on film or in a

23 movie or live for that matter?

24 A On film, on film.

25 Q And is that the basis for any opinions you 04:38

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1 express about the Zeus in -- in your report? 04:38

2 A No, I -- my -- my experience with minimally
3 invasive and robotic surgery goes back so far that when
4 we were shopping for the first surgical robot for our
5 hospital, there were actually two companies on the market 04:39
6 and I'm familiar with the products from both and then I'm
7 aware of the fact that at some point, one of the
8 manufacturers bought the second one and essentially
9 phased out the product. But as I mentioned, I've been in
10 this world for so long actually, it actually goes back to 04:39
11 the time where Zeus was one of the market players.

12 Q Did you do any research or investigation into
13 the efficacy and functioning of the Zeus robot?

14 MR. CORRIGAN: Object to the form.

15 THE WITNESS: I don't know if I've done any formal 04:39
16 research but I've certainly investigated the pros and
17 cons and I will be honest with you, the details of those
18 investigations escape me because they were from decades
19 ago but at some point we were shopping around for --
20 between Zeus and the da Vinci robot. 04:40

21 BY MR. RUBY:

22 Q What can you tell me, if anything, about the
23 Zeus robot and its capacity to process information about
24 haptic, H-A-P-T-I-C, feedback?

25 A Yes, so from my recollection, Zeus robot 04:40

1 Q In person? Over some electronic means? How 05:00
2 did you see it in operation?

3 A I've seen it at one of the hospitals where I
4 was and I'm trying to remember. You asked me that
5 earlier. I don't remember exactly which hospitals and 05:00
6 I've seen it in the videos that I told you, the video
7 that I was referring to earlier.

8 Q The last sentence of this paragraph 22 begins
9 "this has been a disappointing shortcoming."
10 Do you see that? 05:00

11 A Yes.

12 Q And -- and what is the source of that
13 allegation?

14 A My many conversations with surgeons like
15 myself and furthermore, it has been a big sticking point 05:00
16 in the beginning of my experience with da Vinci robotic
17 surgery because it is a very unusual tactile sensation to
18 operate without haptic feedback and the instructors who
19 teach you how to use it, actually tell you when you tie a
20 knot for example and you look at the suture, you want to 05:01
21 see how the fluid is squeezed from that suture when
22 you're tightening it because you can't feel the tension
23 you're -- you're -- you're exerting on the thread. It's
24 very easy to break it. So you have to compensate by
25 other modalities and that is -- it's an accepted 05:01

1 criticism and accepted shortcoming of the device and they 05:01
2 teach you -- actually teach you specific skills on how to
3 overcome it.

4 Q But this is something somebody told you?

5 A That's something I experienced myself. 05:01

6 Q Well, if you look at the sentence at the end
7 of paragraph 22 it ends, "It's been a source of
8 widespread criticism by surgeons who use the da Vinci."

9 Do you see that?

10 A Yes. 05:02

11 Q So surgeons complained to you about this?

12 A I've spoken to many people about it.

13 Q Would you look, please, in your first report,
14 at paragraph 35.

15 A Allow me to read it, please. 05:02

16 (Document reviewed by the witness.)

17 THE WITNESS: Yes, I read it.

18 BY MR. RUBY:

19 Q You say in the first sentence, "There's no
20 reason to treat EndoWrist instruments differently than 05:03
21 their laparoscopic counterparts."

22 Do you see that?

23 A Yes.

24 Q And that's your opinion, right?

25 A Yes. 05:03

1 Q And is the basis for -- is the entire basis 05:03
2 for your opinion in this regard set out in paragraph 35?

3 A I have used many logical points in this
4 report and my other report that support this opinion.

5 Q Well, the -- the principal point you -- you 05:03
6 have made or tried to make is that the da Vinci
7 EndoWrist -- excuse me, the EndoWrist instruments are no
8 different than their lap -- laparoscopic counterparts, if
9 there are any, right?

10 A There are -- 05:04

11 MR. CORRIGAN: Object to the form.

12 THE WITNESS: What I would like to say is that
13 EndoWrist instruments are structurally and functionally
14 similar to their laparoscopic counterparts. Thus, I do
15 not see any reason why they should be treated 05:04
16 differently.

17 BY MR. RUBY:

18 Q Then on the one, two, three, fourth line,
19 you -- you talk about -- strike that.

20 On the fourth line of this paragraph 35, 05:04
21 you -- you say, "And if appropriate, tuned up and
22 returned to use."

23 Do you see that?

24 A Yes.

25 Q Is "tuned up" a medical term? 05:04

A No. The tune up would mean that the instrument is inspected, assessed on what is wrong with it and, if appropriate, repaired and returned to its previous functional status.

5 Q Well, does a tune up, as you use the term, 05:06

6 embrace the replacement of a broken or missing part?

7 A If it's so required but I'm not an engineer
8 to opine on how to repair instruments.

9	Q Have you ever read any submissions made by	
10	Intuitive to the FDA in respect to the usage limitation?	05:06

11 MR. CORRIGAN: Object to the form.

12 THE WITNESS: I have read references to those
13 submissions.

14 BY MR. RUBY:

15 Q But now the question I asked is, have you 05:07
16 ever read any admissions -- any submissions from
17 Intuitive to the FDA in respect to the usage limitation?

18 A The answer to the question is, I have read
19 quotes from those submissions. I have not personally
20 verified the accuracy of those quotes. 05:07

21 Q And -- and in what document or documents did
22 those quotes that you read appear?

23 A Some of the documents provided to me in
24 preparation was a report from a consultant whose last
25 name is, I believe, Troutman who is -- who opined on the 05:07

1 necessity of obtaining FDA clearance for reprocessing 05:07
2 EndoWrist instruments and in it, she quoted some of the
3 data submitted by Intuitive Surgical to FDA to validate
4 the use limits.

5 Q And did you assume that what you read from 05:08
6 this consultant was accurate such that it formed a basis
7 for any opinions you've expressed today?

8 A It did not form the basis for my opinions
9 today. You asked me if I ever read Intuitive Surgical
10 submissions and the answer is yes, I have but not 05:08
11 directly.

12 Q Did you -- did you ever have a research grant
13 from Johnson & Johnson?

14 A I do not recall having a research grant from
15 Johnson & Johnson. 05:08

16 MR. RUBY: Could we mark 263, please.

17 (Whereupon Defendant's Exhibit 262 was
18 marked for identification by the Court
19 Reporter.)

20 MR. RUBY: Could we mark 263, please. 05:10

21 MS. AZHAR: It should populate on your end now.

22 (A pause in the proceedings.)

23 BY MR. RUBY:

24 Q This is the one we're looking at. Has that
25 come up on your screen yet? 05:11

1
2
3 I, THE UNDERSIGNED, DO HEREBY CERTIFY UNDER
4 PENALTY OF PERJURY THAT I HAVE READ THE FOREGOING
5 TRANSCRIPT; THAT I HAVE MADE ANY CORRECTIONS AS APPEAR
6 NOTED, IN INK, INITIALED BY ME, OR ATTACHED HERETO; THAT
7 MY TESTIMONY AS CONTAINED HEREIN, AS CORRECTED, IS TRUE
8 AND CORRECT.

9 EXECUTED THIS _____ DAY OF _____,
10 2023, AT _____, _____.
11 (CITY) (STATE)

12
13
14 _____
15 DR. EUGENE RUBACH
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1
2 I, MICHELLE MEDEL SABADO, RPR, CRR, CSR NO. 7423, IN
3 AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY:

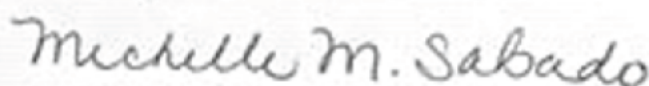
4 THAT PRIOR TO BEING EXAMINED, THE WITNESS NAMED IN
5 THE FOREGOING DEPOSITION WAS DULY SWORN BY ME TO TESTIFY
6 THE TRUTH, THE WHOLE TRUTH, AND NOTHING BUT THE TRUTH;

7 THAT SAID DEPOSITION WAS TAKEN DOWN BY ME IN
8 SHORTHAND AT THE TIME AND PLACE THEREIN NAMED, AND
9 THEREAFTER REDUCED TO TYPEWRITING UNDER MY DIRECTION, AND
10 THE SAME IS A TRUE, CORRECT AND COMPLETE TRANSCRIPT OF
11 SAID PROCEEDINGS;

12 THAT IF THE FOREGOING PERTAINS TO THE ORIGINAL
13 TRANSCRIPT OF AN EXAMINATION IN A FEDERAL CASE, BEFORE
14 COMPLETION OF THE PROCEEDINGS, REVIEW OF THE TRANSCRIPT
15 { } WAS { } WAS NOT REQUIRED.

16 I FURTHER CERTIFY THAT I AM NOT INTERESTED IN THE
17 EVENT OF THE ACTION.

18 WITNESS MY HAND THIS 10TH DAY OF MARCH, 2023.
19
20
21

22 
23

24 MICHELLE MEDEL SABADO

25 RPR, CRR, CSR NO. 7423